2605/102

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ranculoner's Docket No.	2003/102	FAIENI
IN THE UNITED ST	ATES PATENT AND TRADEMA	ARK OFFICE ANG 25 7007 ANG 25 7007
Patent application of		ANG 25 ZOOT
	Inventor(s)	CENTER ISS
for		.000/2900
	Title of invention	
	OR	
In re application of: Toshio Miyata		
Application No.: 10/009,877 Filed: November 13, 2001 For: Blood Carbonyl Compound-Tra	Group No.: 1614 Examiner: Not Yet Assigned pping Agent	
Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450		
WITHIN	MENTAL INFORMATION DISCI THREE MONTHS OF FILING O RST OFFICE ACTION (37 C.F.R	R
CERTIFICATE OF MA	AILING/TRANSMISSION (37 C.F.R. SE	CTION 1.8(a))
I hereby certify that, on the date shown below, the	his correspondence is being:	
MAILING		FACSIMILE
[x] deposited with the United States Postal Serv sufficient postage as first class mail in an envelo addressed to Commissioner for Patents, P.O. Bo Alexandria, VA 22313-1450	pe Office.	imile to the Patent and Trademark
Date:August 25, 2003	Signature Barbara J. Carter, I (type or print name of	 <i>v</i>

(Transmittal of Information Disclosure Statement Within Three Months of Filing or Before Mailing of First Office Action--page 1 of 3)

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OFFICE OF PETITIONS

NOTE:" An information disclosure statement shall be considered by the Office if filed by the applicant: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

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NOTE: The "filing date of a national application" under 37 C.F.R. section 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. section 1.53(b) as "the date on which: (1) A specification containing a description pursuant to section 1.71 and at least one claim pursuant to section 1.75; and (2) any drawing required by section 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by section 1.41." 37 C.F.R. section 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. section 371(c) within the periods set forth in section 1.494 or section 1.495. 35 U.S.C. section 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. section 1.97(b)(2).

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

- NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no
 Office action has been mailed if the disclosure statement is delayed until after three months from filing."
- NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action."

 Notice of April 20, 1992 (1138 O.G. 37-41, 39).
- NOTE: "The term national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).
- NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirement (37 C.F.R. section 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. section 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. section 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

SIGNATURE OF PRACTITIONER

Reg. No. 52,703

Tel. No.: (617) 443-9292

Customer No.: 002101

02605/00103 266554.1

11 000101

Barbara J. Carter, Ph.D. (type or print name of practitioner)

125 Summer Street, 11th Floor

P.O. Address

Boston, MA 02110

3 of 3)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Patent application	TECH CENTER 1800/200
ofInvento	
for	· · · · · · · · · · · · · · · · · · ·
Title of in	vention
the specification of which is being transmitted herewith OR	
In re application of: Toshio Miyata	
Application No.: 10/009,877 Group No.: Filed: November 13, 2001 Examiner: For: Blood Carbonyl Compound-Trapping Agent	1614 Not Yet Assigned.
Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
	(Information Disclosure Statementpage 1of 9)
I hereby certify that, on the date shown below, this correspondence MAILI	· .
[x] deposited with the United States Postal Service in an envelope address 22313-1450	sed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA
37 C.F.R. SECTION 1.8(a)	37 C.F.R.SECTION 1.10*
[x] with sufficient postage as first class mail. TRANSMI	☐as "Express Mail Post Office to Addressee" Mailing Label No (mandatory) SSION
☐transmitted by facsimile to the Patent and Trademark Office.	
. Date:August 25, 2003	Signature Sale Sarbara J. Carter, Ph.D. (type or print name of person certifying)
*WARNING: Each paper or fee filed by "Express Mail" must thereon prior to mailing. 37 C.F.R. section 1.10	t have the number of the "Express Mail" mailing label placed 0(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT



"An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
 (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international stage. application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Supplemental Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

- 1. [x]Preliminary Statements
- 2. [x]Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
- 3. Statement as to Information Not Found in Patents or Publications
- 4. [Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
- 5. []Cumulative Patents or Publications
- 6. [x]Copies of Listed Information Items Accompanying This Statement
- 7. []Concise Explanation of Non-English Language Listed Information Items
 - 7A. []EPO Search Report
 - 7B. []English Language Version of EPO Search Report
- 8. [x]Translation(s) of Non-English Language Documents
- 9. []Concise Explanation of English Language Listed Information Items (Optional)
- 10. [x]Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections

, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

(Information Disclosure Statement--page 2 of 9)

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Section 1. Preliminary statements



Applicants submit herewith patents, publications or other information, of which they are a ware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.





Applicants:

Toshio Miyata

Attorney Docket:

2605/102 TECH CENTER 1600/2900

Serial No:

10/009,877

Art Group Unit:

Date Filed:

November 13, 2001

Examiner Name:

Not Yet Assigned.

Invention:

Blood Carbonyl Compound-Trapping Agent

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. PATENT DOCUMENTS					
Examiner					
Initials	itials Number				
	AN	US4,977,287	12/11/90	Kakimoto, et al.	556/83

			FOREIGN PATENT I	DOCUME	NTS	
Exam. Initials	Ref. No.	Country Code	Doc. No.	Public. Date	Patentee or Applicant	Class/Subclass
	AO	JР	62-142114, A *See Ref. No. DC for Corresponding EP Appln.	6/25/87	Cerami, A., et al.	A61K31/155
	AP	JP	62-249908, A	10/30/87	Fujimoto, D., et al.	A 61K 7/00
	AQ	JP	64-056614, A	3/3/89	Ouchida, S., et al.	A 61K 31/155
	AR	JP	64-083059, A	3/28/89	Ouchida, S., et al.	C07C143/72
	AS	JP	2-156, A *See Ref. No. DD for Corresponding EP Appln.	1/5/90	Cerami, A., et al.	C07281/16
	AT	JP	2-765, A	1/5/90	Ouchida, S., et al.	C07C281/16
	AU	JP	2-42053, A *See Ref. No. DE for Corresponding EP Appln.	2/13/90	Ouchida ,S., et al.	C07C281/16
	AV	JP	6-9380	1/18/94	Williamson ,J.R., et al.	A61K 31/155
	AW	JP	10-167965, A	6/23/98	Yasumura, K., et al.	A61K 31/415
	AX	JP	6-192089, A	7/12/94	Niigata, K., et al.	A61K 31/41
	AY	JP	6-298737, A	10/25/94	Niigata, K., et al.	C07D231/14
	AZ	JP	6-298738, A	10/25/94	Niigata, K., et al.	C07D231/38
	BA	JP	5-201993	8/10/93	Miyajima, K., et al	C07D233/88
	BB	JP	6-135968, A	5/17/94	Kurono, M., et al.	C07D491/107
	BC	JP	7-133264, A	5/23/95	Yasumura, K., et al.	C07D233/88
	BD	JP	10-182460, A	7/7/98	Hotta, A., et al.	A61K 31/415
	BE	JP	4-9375, A	1/14/92	Soda, T., et al.	C07D277/48
	BF	JP	9-59258, A	3/4/97	Matsui, T., et al.	C07D233/88
	BG	JP	3-261772, A	11/21/91	Sumoto, K., et al.	C07D277/06
	ВН	JP	8-157473, A *See Ref. No. DF for Corresponding WO Appln.	6/18/96	Ohara, Y., et al.	C07D417/06

(Information Disclosure Statement--page 4 of 9)

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	(BI	JP	10-158244, A	6/16/98	Iyobe, A., et al.	AUG 2 8 20 C07D213/65
رکين.	BJ	JP	10-175954, A	6/30/98	Iyobe, A., et al.	G97D213/65
EMPON	BK	JP	6-287180, A	10/11/94	Niigata, K., et al.	C07D231F36600
	BL	JP	6-305964	11/1/94	Yasumura, K., et al.	A61K 31/415
	BM	JP	3-161441, A *See Ref. No. DG for Corresponding EP Appln.	7/11/91	Inoue, J.	A61K31/47
	BN	JP	7-196498, A	8/1/95	Zuckerman, S.H.	A61K31/40
	ВО	JP	3-204874, A	9/6/91	Ouchida, S., et al.	C07D311/72
	BP	JP	4-308586, A	10/30/92	Ouchida, S., et al.	C07D311/04
	BQ	JP	2-167264, A *See Ref. No. DH for Corresponding EP Appln.	6/27/90	Soda, T., et al.	C07D213/74
	BR	JP	3-148220, A	6/25/91	Kurozumi, M., et al.	A61K 31/41
	BS	JP	5-9114, A	1/19/93	Hayakawa, M., et al.	A61K 31/12
	BT	JP	5-310565 A	11/22/93	Ulrich, P.C., et al.	A61K 31/16
	BU	JP	62-249909, A *See Ref. No. DI for Corresponding EP Appln.	10/30/87	Nagaoka, Y., et al.	A61K7/00
	BV	JP	2-62885, A *See Ref. No. AN for Corresponding US Patent	3/2/90	Kakimoto, N., et al	C07F7/30
	BW	JP	5-255130, A	10/5/93	Kakimoto, N., et al	C07B63/04
	BX	JР	7-247296, A	9/26/95	Kakimoto, N., et al	C07F7/30
	BY	JP	8-59485, A	3/5/96	Sawai, K., et al.	A61K31/80
	BZ	JP	3-240725, A	10/28/91	Morisake, M., et al	A61K31/35
	CA	JP	7-206838, A	8/8/95	Hosokawa, T.,	C07D307/32
	CB	JP	9-241165, A	9/16/97	Takahashi, H., et al.	A61K31/70
	CC	wo	94/04520 A1	3/3/94	Hosokawa, T.,	C07D307/32
	CD	JP	6-206818, A	7/26/94	Schoenafinger, K., et al.	A61K31/425
	CE	JP	9-59233, A	3/4/97	Sato, F., et al.	C07C229/36
	CF	JP	9-40626, A	2/10/97	Sato, F., et al.	C07C237/20
	CG	JP	9-124471, A	5/13/97	Sato, F., et al.	A61K31/135
	СН	JP	6-305959	11/1/94	Hosokawa, T.,	A61K31/19
	CI	wo	91/11997, A1	8/22/91	Inoue, J.	A61K31/195
	CJ	JP	10-158265, A	6/16/98	Nakazawa, Y., et al.	C07D471/16
	CK	wo	97/09981 A1	3/20/97	Hudson, B.G., et al	A61K31/425
	CL	JP	6-256280, A	9/13/94	Golub, L.M., et al.	C07C237/26
	CM	JP	9-221427, A	8/26/97	Ito, M.	A61K31/73
	CN	JP	9-40519, A	2/10/97	Uchino, K., et al.	A61K7/00
	co	JР	20753, A	1/5/90	Ouchida, S., et al.	C07C243/28
	CP	JP	5-505189, A *See Ref. No. CX	8/5/93	Meglasson, M.D.	A61K31/19
			for Corresponding WO Appln.			
,	CQ	JP	7-500811, A *See Ref. No. CY for Corresponding WO Appln.	1/26/95	Ulrich, P.C., et al.	C07D239/42
	CR	JP	4-502611, A *See Ref. No. CZ Corresponding WO Appln.	5/14/92	Grigg, G.W., et al.	A61K37/02
	CS	JP	7-503713, A *See Ref. No. DA for Corresponding WO Appln.	4/20/95	Ulrich, P.C., et al.	A61K31/195
	CT	JP	7-500580, A *See Ref. No. DB for Corresponding WO Appln.	1/19/95	Michaelis, J., et al.	A61K38/00

(Information Disclosure Statement--page 5 of 9)

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13	CU	JP	9-315960, A.	12/9/97	Mizuno, T., et al.	A61K31/12
No. C.	CV	JP	6-287179, A	10/11/94	Niigata, K., et al.	C07D2721/08
300	CW	EP	0474874, A1	3/18/92	Inoue, J.	A61K31/195
	CX	wo	91/12800, A1	9/5/91	Meglasson, M.D.	A61K31/195
	CY	wo	92/11853, A1	7/23/92	Ulrich, P.C., et al.	A61K31/505
	CZ	wo	90/06102, A1	6/14/90	Grigg, G.W., et al.	A61K7/40
	DA	wo	93/14750, A1	8/5/93	Ulrich, P.C., et al	A61K31/195
	DB	wo	93/04690, A1	3/18/93	Michaelis, J., et al.	A61K37/02
	DC	EP	0222313, A2	5/20/87	Cerami, A., et al.	A61K31/55
	DD	EP	0316852, A2	5/24/89	Ulrich, P.C., et al.	A61K31/155
	DE	EP	0339496, A2	11/2/89	Ohuchida, S., et al. [sic]	C07C133/10
	DF	wo	96/11196, A1	4/18/96	Ohara, Y., et al.	C07D417/14
	DG	EP	0433679, A2	6/26/91	Inoue, J.	A61K31/535
	DH	EP	0359112, A2	3/21/90	Sohda, T., et al.	C07D277/42
	DI	EP	0242855, A2	10/28/87	Nagaoka, Y., et al.	A61K7/48

	OTHER DOCUMENTS			
Exam. Initials	Ref. No.	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date	
	DJ	Miyata, T., et al.	Implication of an Increased Oxidative Stress in the Formation of Advanced Glycation End Products in Patients with End-Stage Renal Failure, <i>Kidney International</i> , Vol. 31 (1997) pp. 1170-1181	
	DK	Foote, E.F., et al.	The Pharmacokinetics of Aminoguanidine in End-Stage Renal Disease Patients on Hemodialysis, <i>American Journal of Kidney Disease</i> , Vol. 25, No. 3 (March) 1995: pp. 420-425	
	DL	Nakamura, S., et al.	Progression of Nephropathy in Spontaneous Diabetic Rats is Prevented by OPB-9195, a Novel Inhibitor of Advanced Glycation, <i>Diabetes</i> , Vol. 46, May 1997, pp 895-899	
	DM	Rahbar, S.	An Abnormal Hemoglobin in Red Cells of Diabetics, Clin. Chim. Acta., 22 (1968) 296-298	
	DN	Miyata T., et al.	Accumulation of Albumin-Linked and Free-Form Pentosidine in the Circulation of Uremic Patients with End-Stage Renal Failure: Renal Implications in the Pathophysiology of Pentosidine, <i>Journ. of the Amer. Society of Nephrology</i> , Vol. 7, Number 8, 1996	
	DO	Maillard LC.	Reaction Generale Des Acides Amines Sur Les Sucres: Ses Consequences Biologiques, Societe de Biologie, April 20, p. 599-603	

Examiner Signature:	
Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is in confoline through citation <i>if not</i> in conformance and not considered. Include copy of communication to applicant.	•

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include:

"A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included..."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

[]Exception(s) to above:
[]Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
[]Cumulative patents or publications identified in Section 5.

Section 8. Translation(s) of Non-English Language Documents

NOTE: "If a written English language translation of a non-English language document, or portion thereof, is within the possession, custody or control of, or is readily available to any individual designated in section 1.56(c), a copy of the translation shall accompany the statement." 37 C.F.R. section 1.98(c).

NOTE: "The Office does not intend to require translations unless they have been reduced to writing and are actually translations of what is contained in the non-English language information. Applicants should note, however, that most examiners do not have the ability to understand information which is not in English and that the Office will not routinely translate information submitted in a non-English language. The examiner will consider the information insofar as it is understood on its face, e.g., drawings, chemical formulas, English language abstracts, but will not have the information translated unless it appears to be necessary to do so. Applicants are required to aid the examiner by complying with the requirements for a concise explanation in section 1.98(a)(3) for information submitted in a non-English language." Notice of January 9, 1992, 1135 O.G. 13-25, at 21.

NOTE: "The examiner will indicate that the non-English language information has been considered in the same manner as consideration is indicated for information submitted in English." Notice of April 20, 1992 (1138 O.G. 37-41, 41).

[x] Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material:

DO

(complete the following, if applicable)

- [] No English language translations of the foreign language patents, publications or information or parts thereof are readily available, except for those listed above.
- [x] The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith.

Foreign	English
AO	DC (EP Application)
AS	DD (EP Application)
AU	DE (EP Application)
BH	DF (WO Application)
BM	DG (EP Application)
BQ	DH (EP Application
BU	DI (EP Application)
BV	AN (US Application)
CP	CX (PCT Application)
CQ	CY (PCT Application)
CR	CZ (PCT Application)
CS	DA (PCT Application)
CT	DB (PCT Application)

(Information Disclosure Statement--page 8 of 9)

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DEC 1 1 2003

OFFICE OF PETITIONS

Section 10. Identification of Person(s) Making This Supplemental Information Disclosure Statement

The person making this certification is	
(check each applicable item)	
(a) []the inventor(s) who signs below	
	SIGNATURE OF INVENTOR
	(type name of inventor who is signing)
(b) []an individual associated with the fil 1.56(c))	ing and prosecution of this application (37 C.F.R. section
	SIGNATURE OF INVENTOR
	(type name of inventor who is signing)
(c) [x] the practitioner who signs below on	the basis of the information:
(check each applicable item)	
[] supplied by the inventor(s).
[] supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).	
[x] in the practitioner's file.	
	Bale 1 Get
Reg. No.: 52,703	SIGNATURE OF PRACTITIONER
	Barbara J. Carter, Ph.D. (type or print name of practitioner)
Tel. No.: (617) 443-9292	105 C Ath Th
	125 Summer Street, 11 th Floor P.O. Address
Customer No.: 002101	
02605/00102 266503.1	Boston, MA 02110